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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/081,641 | 02/22/2002 | Patrick A. Haverkost | BSI-486US | 2371 |

7590 09/29/2005

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| EXAMINER |
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WEBB, SARAH K

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| ART UNIT | PAPER NUMBER |
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3731

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|--------------------------------------|---|--|
| Office Action Summary | Application No. 10/081,641 | Applicant(s) HAVERKOST ET AL. | |
| | Examiner Sarah K. Webb | Art Unit 3731 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-51 is/are pending in the application.
- 4a) Of the above claim(s) 9, 12-16, 18-29, 34-46 and 48-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-8, 10, 11, 17, 30-33, 47 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1,3-8,10,11,17,30,32,47, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,201,757 (Heyn et al) in view of US Patent No. 6,042,589 (Marianne).

Heyn discloses a stent introducer (Figures 2 and 4) that includes a shaft (78) with a distal tip (84), inner sheath (100), stent (106), antegrade sheath (82) attached to the distal tip (84), and a retrograde sheath (94). The antegrade sheath (30) and the retrograde sheath (20) are moveable between the positions of abutting one another and being laterally spaced from one another. The antegrade sheath (30) is axially moveable in a distal direction by distally moving the shaft (44), since the sheath (30) is connected to the shaft (44) by way of distal tip (40) (column 5, lines 30-35 and column 6, lines 27-29). Heyn also includes an anchoring means in the form of detent (104) in the retrograde portion for preventing axial movement of the stent. Regarding claims 10 and 11, a "radial spacer" attached proximal to the distal tip provides space between the inner sheath (100) and the antegrade sheath (82).

Heyn includes all the limitations of the claimed invention, but fails to form the anchoring means as a balloon. Marianne discloses a stent (7) introducer with a retracting sheath (16) and a proximal anchoring means in the form of a balloon (20).

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Marianne teaches that a balloon positioned in the retrograde portion of the stent provides better control of the stent during placement. The balloon prevents axial movement of the stent during retraction of the sheath for deployment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to replace the anchoring detent of Heyn with a balloon, as taught by Marianne, in order to provide better control of the stent during the placement procedure. The balloon is also capable of anchoring the stent in the body lumen, as Marianne explains that the balloon can be used to reposition the stent in the body lumen (column 3, line 35). Figures 4 and 5 clearly illustrate the balloon anchoring the stent against the lumen of a vessel.

Marianne further teaches that an inner sheath mounted over the shaft (8) can define an inflation lumen (22) for the balloon (20) (column 4, line 10). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teaching of Marianne to adapt the inner sheath of Heyn to define an inflation lumen for the balloon of the device, as modified above.

Regarding claims 7, 8, and 17: The modified Heyn device fails to include a medial sheath. In Figure 13 of Heyn, a medial sheath (246) is located between the inner and retrograde sheaths. It terminates proximally to the stent. Heyn teaches that such a "medial sheath" (246) can be provided as a proximal stop for the stent (column 11, line 27) so that it won't travel into the proximal region of the device. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a medial sheath in the modified Heyn device in order to prevent the stent from traveling proximally into the device.

2. Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heyn in view of US Patent No. 5, 445, 646 (Euteneuer).

Heyn includes all the limitations of claims 31 and 33, except for making the anterograde sheath cover more of the stent than the retrograde sheath and overlapping the two sheaths. Euteneuer discloses a stent introducer in Figure 2 that is similar to Heyn. The device includes both a retrograde (14) and an anterograde (16) sheath. The anterograde sheath covers a greater portion of the stent than the retrograde sheath in order to provide an overlapping region. Euteneuer explains that the overlap forms a seal (column 6, lines 47-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to lengthen the anterograde sheath of Heyn so that it overlaps the retrograde sheath, as Euteneuer teaches that this structure forms a seal around the stent.

Response to Arguments

3. Applicant's arguments filed 7/11/05 regarding the 103 rejections under Heyn and Marianne have been fully considered but they are not persuasive. Applicant's arguments are based on the intended use of the device. The claims recite language directed toward the intended method of deployment of the stent using the introducer, such as "*anchoring the endoluminal device proximal end after expansion of the proximal end*" and "*minimizing relative axial movement between the proximal end of the device and the body lumen during unsheathing of a remaining portion of the endoluminal device distal of the proximal end.*" A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If

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the prior art structure is capable of performing the intended use, then it meets the claim. The modified Heyn device includes all the structural requirements and is capable of being manipulated in the same manner as claimed, in which the retrograde sheath is retracted first to deploy the proximal end of the stent, the anchoring balloon is inflated, and the anterograde sheath is lastly moved distally to deploy the remaining portion of the stent. Figures 4, 5, and 6 of Marianne illustrate that the balloon can be expanded to a diameter that allows it to engage an expanded stent.

Conclusion

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K. Webb whose telephone number is (571) 272-4706. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW

9/27/05

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER